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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,565	10/11/2001	Catherine S. Levisage	55322 (71699)	7490
21874	7590	06/15/2004	EXAMINER	
EDWARDS & ANGELL, LLP			FUBARA, BLESSING M	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	
			1615	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/975,565	Applicant(s) LEVISAGE ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 35-52 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14-27 and 35-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks, all filed 04/05/04.

Regarding applicants' election as remarked in the last office action, although applicants did not identify the claims that read on the elected paclitaxel, claims that read on paclitaxel were examined. Claim 15 was also examined because the prior art teaches 5-fluorouracil. Claims 12 (directed to peptide or polypeptide), 13 (directed to protein) and 21 were withdrawn from examination. Thus claims 1-11 and 22-43 were examined. However, claim 21 and the claim dependent from claim 21 are now examined because claim 21 as amended depends from claim 8, which was previously examined and now examined. Thus claims 1-11, 21-27 and 35-52 are now examined.

Claim 1 is currently amended to recite mean particle size of between 0.5 μm and about 100 μm . Claims 28-34 are cancelled and new claims 44-52 added.

Claim Objections

1. The objection of claims 8-11, 22-27, 35 and 36 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn because the amendment to the claims overcomes the objection.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-11, 14-20, 22-27, 35 and 36 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention is withdrawn because applicants' statements regarding the issue raised is persuasive.

Claim Rejections - 35 USC § 102

3. The rejection of claims 1-11, 14-20, 22-27 and 35-43 under 35 U.S.C. 102(e) as being anticipated by Bru-Magniez et al. (US 6,211,273) is not maintained because the generic claim 1 recites a mean particle size of between 0.5 μm and about 100 μm .

However, these claims are obvious over the prior art of record and a rejection under 35 USC 103 is made below. New claims 44-52 are included in the rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-11, 14-27 and 35-52 rejected under 35 U.S.C. 103(a) as being unpatentable over Bru-Magniez et al. (US 6,211,273).

Bru-Magniez discloses a nanoparticles of polymeric support material network within which therapeutic agents such as taxol and 5-fluorouracil are dispersed (abstract, column 2, lines 35-50, column 5, lines 3-35 and column 6, lines 25-36). The disclosed polymer network meets the polymer structure of the instant claims and the prior art specifically discloses methyldiene malonate nanoparticles (column 2, lines 15-17 and Title). The instant method comprises administering the polymeric composition. The prior art administers the composition orally,

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sublingually, subcutaneously, intramuscularly, intravenously, transdermally, locally, rectally, via the pulmonary route, or nasally; preferred forms of administration notably comprise oral forms, such as tablets, gelatin capsules, powders, granules and oral solutions or suspensions, sublingual and buccal administration forms, as well as subcutaneous, intramuscular intravenous, intranasal or intraocular and rectal administration forms (column 6, lines 43-53). It is inherent that the administered composition comprising an anticancer drug would inherently provide the desired effect. The nanoparticles of Bru-Magniez have diameter of less than 500 nm and particles having diameter of 100-500 nm are preferred (column 3, line 67 to column 4 line 1). The method of preparing the particles of Bru-Magniez involves preparing a solution of the polymer in a water miscible organic solvent, adding with stirring, the organic phase to an aqueous polymerization medium at a pH between 4.5 and 10, homogenizing the mixture, evaporating the organic solvent in vacuo to recover/collect the nanoparticles (column 4, lines 5-13). In another embodiment, the polymer precipitates in the polymerization medium, the polymer is recovered by filtration and the suspension or filtrate of the nanoparticles is "conditioned and lyophilized" (column 4, lines 14-36). It is noted that the process of recovering precipitates by filtration routinely involves wash cycle(s).

Bru-Magniez discloses the composition and method for preparing the composition. The difference between the prior art and the instant claims is the size of the particles. The prior art discloses particle diameter of less than 500 nm, which is 0.5 μm . The lower limit of the mean particle diameter of the particle is about 0.5 μm . However, there is no demonstration that a microparticle having a mean particle diameter of about 0.5 μm provides unusual results. A mean particle diameter of about 0.5 μm is not critical over a mean particle diameter of less than 0.5 μm

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in the absence of a showing of criticality. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the nanoparticle of Bru-Magniez. One having ordinary skill in the art would have been motivated to prepare nanoparticles of methylidene malonate having a diameter of less than 500 nm or 100-500 nm with the expectation that the medicament dispersed within the polymer is delivered to a subject.

Applicants argue that the instant claims are directed to microparticles having mean particle size of between 0.5 μm and 100 μm while the prior art discloses nanoparticles having average particle size of less than 500 nm, which is 0.5 μm . Applicants then contend that the Bru-Magniez compositions do not satisfy the requirements of the instant claim.

Response to Arguments

6. Applicants' arguments filed 04/05/04 have been fully considered but they are not persuasive.

Examiner recognizes that the range of the particle size of the prior art is outside the range of the particle size of the instant claim. However, Examiner takes the position that both the prior art and the instant claims are in the same field of endeavor solving the same problem. The particles of the prior art are used for applicants' purpose. Applicants provided no evidence that a particles size of 0.5 μm is a critical and unusual limitation in applicants' polymeric composition.

No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

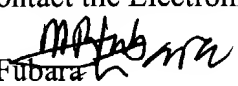
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Blessing Fubara
Patent Examiner
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